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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,016	03/24/2001	Mark B. Lyles	068986.0107	5726

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EXAMINER
PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
1641	9

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/817,016	LYLES, MARK B.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 41-48 and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasukawa et al. (US Pat. 5,629,186). The reference discloses a porous matrix and methods of its production. Fused fibrous ceramic materials are prepared from amorphous silica and/or alumina fibers with 2 to 12% boron nitride. The matrix may be used as a cell-culture substrate, as an implant material, and for chromatographic separation of blood cells (abstract). The matrix may have a density between 3.5 and 5.5 pounds per cubic foot. In one embodiment, the fibers have diameters between 0.5 and 5 microns. Fur use as an implantable material, the matrix may be coated with a biocompatible material at its outer surface. Fur use in affinity chromatography, the fibers may be derivatized with molecules effective to bind ligand molecules passed through the matrix (Col. 1). Since alumina is an optional component of the matrix, it is inherent that silica may form greater than 50% of the surface of the matrix.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 41-48 and 56-61 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lyles et al. (WO 96/24631).

The reference discloses or teaches dental materials comprising from about 1% to 50% by weight alumina, 50% to 90% by weight silica, and 1% to 5% by weight boron. In preferred embodiments, the composition may 2.85% boron nitride. The mean pore diameter of the material is greater than 10 microns (page 20). The density of the material may be from 4 up to 62 pounds per cubic foot (page 5). According to the reference, silanization improves the fiber to resin bond.

If the preamble of the claim is not given patentable weight, as is generally the case, the reference anticipates the claims because it discloses all the elements of the claims to which it was applied. However, if the preamble is given weight, the reference renders the claimed invention *prima facie* obvious. Silica is well known in the art in diagnostic systems. For example, glass microscopic slides, which are considered to be diagnostic, are often made of silica. In addition, as evidenced by US Pat. 6,100,966 above, porous silica carriers are known to be used in test devices. As such, one would have had a reasonable expectation of success in using the

composition of Lyles et al. for diagnostic purposes, especially when considering that silica, alumina, and boron all have conducting properties.

6. Claims 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al. (US Pat. 5,629,186) or Lyles et al. (WO 96/24631) in view of Beattie (US Pat. 5,843,767).

Yasukawa et al. and Lyles et al. teach devices or compositions, as previously discussed. However, the references do not teach immobilization of oligonucleotides or DNA.

Beattie teaches attachment of oligonucleotides and DNA to silicon dioxide (silica).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize oligonucleotides or DNA as taught by Beattie with the devices and composition of Yasukawa et al. or Lyles et al. because Beattie teaches that these molecules can be successfully attached to surfaces comprising silica. In addition, Yasukawa et al. specifically state that the matrix may be coated with biocompatible material on its surface.

7. Claims 50-51 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al. (US Pat. 5,629,186) or Lyles et al. (WO 96/24631) in view of Shivashankar et al. (US Pat. 6,139,831).

Yasukawa et al. and Lyles et al. teach devices or compositions, as previously discussed. However, the references do not teach immobilization of DNA or RNA.

Shivashankar et al. teach the immobilization of DNA, RNA, and carbohydrates to silica.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize DNA, RNA, or carbohydrates as taught by Shivashankar et al. with the devices and composition of Yasukawa et al. or Lyles et al. because Shivashankar et al. teach that these molecules can be successfully attached to surfaces comprising silica. In addition,

Yasukawa et al. specifically state that the matrix may be coated with biocompatible material on its surface.

8. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al. (US Pat. 5,629,186) or Lyles et al. (WO 96/24631) in view of Blake et al. (US Pat. 5,439,792).

Yasukawa et al. and Lyles et al. teach devices or compositions, as previously discussed. However, the references do not teach immobilization of peptides.

Blake et al. teach attachment of peptides to solid phases that may comprise silica.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize peptides as taught by Blake et al with the devices and composition of Yasukawa et al. or Lyles et al. because Blake et al. teach that peptides can be successfully attached to surfaces comprising silica. In addition, Yasukawa et al. specifically state that the matrix may be coated with biocompatible material on its surface.

9. Claims 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al. (US Pat. 5,629,186) or Lyles et al. (WO 96/24631) in view of Schoning et al. (US Pat. 5,874,047).

Yasukawa et al. and Lyles et al. teach devices or compositions, as previously discussed. However, the references do not teach immobilization of proteins or antibodies.

Schoning et al. teach silicon based biosensors comprising porous silicon. The mean pore diameter is 1 nm – 100 um. The porous layer is covered by a layer of silicon dioxide (abstract). Biological structures such as enzymes, protein, antibodies, and others can be crosslinked in the porous layer.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize antibodies and proteins as taught by Schoning et al. with the devices and composition of Yasukawa et al. or Lyles et al. because Schoning et al. teach that proteins and antibodies can be successfully attached to surfaces comprising silica. In addition, Yasukawa et al. specifically state that the matrix may be coated with biocompatible material on its surface.

10. Claims 56-57 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al. (US Pat. 5,629,186). The reference teaches a porous matrix, as previously discussed. However, the reference does not teach the specific percentages of alumina or silica or a density of 6 pounds per cubic foot.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to specify the percentage of alumina or silica as between 1-50% and 50-98%, respectively, because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In addition, it would have also been obvious to make a material with a density of 6 pounds per cubic foot because the reference teaches a density of up to 5.5, and one would have had a reasonable expectation of success in making a material that is only a little denser. There is no reason to believe that a half-pound increase in density would adversely affect the device of the reference in any way.

Response to Arguments

11. Applicant's arguments filed 4/14/03 have been fully considered but they are not persuasive. Applicant has only mage general conclusions that the present claims differentiate

over the prior art, without any basis for these assertions, which renders this position prima facie unconvincing.

Conclusion

Claims 41-61 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

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June 25, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

06/25/03